EMA/812167/2018

European Medicines Agency decision

P/0358/2018

of 7 December 2018

on the acceptance of a modification of an agreed paediatric investigation plan for lasmiditan, (EMEA-002166-PIP01-17-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0167/2018 issued on 15 June 2018,

Having regard to the application submitted by Eli Lilly and Company Ltd on 13 July 2018 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 October 2018, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for lasmiditan, tablet, orodispersible tablet, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Eli Lilly and Company Limited, Lilly Research Centre, Erl Wood Manor, Sunninghill Road, GU20 6PH - Windlesham, Surrey, United Kingdom.

EMA/PDCO/502287/2018
London, 19 October 2018

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002166-PIP01-17-M01

Scope of the application

Active substance(s):

Lasmiditan

Condition(s):

Treatment of migraine headaches

Pharmaceutical form(s):

Tablet

Orodispersible tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Eli Lilly and Company Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Eli Lilly and Company Ltd submitted to the European Medicines Agency on 13 July 2018 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0167/2018 issued on 15 June 2018.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 21 August 2018.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of migraine headaches

The waiver applies to:

- the paediatric population from birth to less than 6 years;
- tablet, orodispersible tablet, oral use;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric investigation plan

2.1. Condition:

Treatment of migraine headaches

2.1.1. Indication(s) targeted by the PIP

Acute treatment of migraine with and without aura

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 6 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Tablet

Orodispersible tablet

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of a bioequivalent orodispersible tablet with effective taste mask
Non-clinical studies	1	**Study 2** Definitive juvenile toxicity study in rats (353404)
Clinical studies	3	**Study 3** Open-label, single dose pharmacokinetic and tolerability study of lasmiditan in paediatric subjects from 6 to less than 18 years old with a history of migraine headache (H8H-MC-LAHX)

		Study 4 Randomized, double-blind, placebo-controlled, parallel-group study to assess efficacy and safety of lasmiditan in paediatric subjects from 6 to less than 18 years old with migraine (H8H-MC-LAHV) **Study 5** Open label, long-term safety study of lasmiditan in paediatric subjects from 6 to less than 18 years of age with migraine with or without aura who have completed Study 3 or 4 (H8H-MC-LAHW)
Extrapolation, modelling and simulation studies	1	**Study 6** Modelling and simulation study for initial paediatric dose finding
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By November 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes